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HITCHCOCK EVERT LLP P.O. BOX 131709 DALLAS, TX 75313-1709			BRANDT, ADAM CURTIS	
			ART UNIT	PAPER NUMBER

3743

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,428

Applicant(s)

FARAM, JOSEPH DEE

Examiner

Adam Brandt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/22/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☒ Claim(s) 2,5,11,12,18,24,25,29,35,36,38,47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities: Evacuation reservoir tube (48) is not mentioned in the specification but is shown in figure 6. Ventilator circuit Y patient connector (47) is not mentioned in the specification but is shown in figure 7. Please include these elements in the appropriate areas of the specification for discussion.

Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "5" has been used to designate both "Connector Tee" and "Injector Nozzle." Figure 1 shows the connector tee labeled as (5). Figure 4 shows the injector nozzle labeled as (5). Please specify your selection.

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4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show “Tube” (39) in figure 6 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 2, 38 are objected to because of the use of “The optimal settings.” “The optimal settings” lacks antecedent basis.

6. Claims 5, 18, 29 are objected to because the wording of the claim is unclear. The examiner does not understand the use of “at least one of automatically...”. The examiner

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interpreted the claim as follows; “The apparatus according to claim 1, further including a timing device that can at least automatically turn off said apparatus at end of therapy session or trigger an alarm to notify patient that treatment session is over.”

7. Claims 11, 24, 35, 47 are objected to because of the use of “the components.” “The components” lacks antecedent basis.
8. Claim 12, 25, 36, 48 are not fully understood because of the objection to claim 11.
9. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. Claims 1, 9, 11, 13-15, 22, 26, 32, 33, 37, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bird (USPN 4,592,349; ‘Bird’).

11. In regards to claim 1: Bird discloses a continuous high-frequency oscillation breathing treatment apparatus comprising a source of gas under pressure (Bird column 6, lines 1-3); a reduction regulator (Bird column 6, lines 46-48) for regulating the flow from gas source; means for interrupting continuous positive gas flow at a rate of least 1 hertz and at most 15 hertz (Bird column 9 line 60 to column 17 line 65. Bird is fully capable of meeting the claim limitations of at least 1 hertz and at most 15 hertz because of ability to adjust the frequency of oscillation; Bird column 34 lines 51-56), whereby the gas flow becomes pulsatile (Bird column 1 lines 26-29) with a substantially constant pressure amplitude; a patient interface circuit that incorporates a fixed venturi tube (Bird column 7 lines 52-53) , encased in a shroud with at least one aperture of predetermined size (Bird column 29 lines 44-58), open to the ambient to allow to allow ingress and egress of flow, and an aerosol entrainment port (Bird column 30 lines 4-18) connectable to a

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nebulizer for entrainment of aerosol (Bird column 30 lines 29-61); said means for interrupting continuous gas flow in combination with said at least one aperture calibrated to allow exhalation and prevent stacking of successive volumes of gas in the airway of the patient (Bird column 29 line 62 to column 30 line 16).

12. **In regards to claim 9:** Bird discloses a breathing treatment apparatus cited in paragraph 11. Additionally, Bird discloses that said patient interface circuit (figure 10) is, at least one of, connected to and incorporated with in a ventilator circuit (Bird, ABSTRACT).

13. **In regards to claim 13:** Bird discloses a patient interface circuit for use with a continuous high frequency oscillation breathing treatment apparatus comprising a fixed venturi tube (Bird column 7 lines 52-53) , encased in a shroud with at least one aperture of predetermined size (Bird column 29 lines 44-58), open to the ambient to allow to allow ingress and egress of flow, and an aerosol entrainment port (Bird column 30 lines 4-18) connectable to a nebulizer for entrainment of aerosol (Bird column 30 lines 29-61); said at least one aperture of patient interface circuit calibrated with continuous high-frequency oscillation breathing treatment apparatus to allow exhalation and prevent stacking of successive volumes of gas in the airway of the patient (Bird column 29 line 62 to column 30 line 16).

14. **In regards to claim 14:** Bird discloses a continuous high-frequency oscillation breathing treatment apparatus comprising a source of gas under pressure (Bird column 6, lines 1-3); a reduction regulator (Bird column 6, lines 46-48) for regulating the flow from gas source; means

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for interrupting continuous positive gas flow at a predetermined, pre-set rate (Bird column 79, lines 47-50. Bird is fully capable of pre-setting at a predetermined configuration of the knobs.) of least 1 hertz and at most 15 hertz (Bird column 9 line 60 to column 17 line 65. Bird is fully capable of meeting the claim limitations of at least 1 hertz and at most 15 hertz because of ability to adjust the frequency of oscillation; Bird column 34 lines 51-56), whereby the gas flow becomes pulsatile (Bird column 1 lines 26-29) with a substantially constant pressure amplitude ; a patient interface circuit that incorporates a fixed venturi tube (Bird column 7 lines 52-53) , encased in a shroud with at least one aperture of predetermined size (Bird column 29 lines 44-58), open to the ambient to allow to allow ingress and egress of flow, and an aerosol entrainment port (Bird column 30 lines 4-18) connectable to a nebulizer for entrainment of aerosol (Bird column 30 lines 29-61); said means for interrupting continuous gas flow in combination with said at least one aperture calibrated to allow exhalation and prevent stacking of successive volumes of gas in the airway of the patient (Bird column 29 line 62 to column 30 line 16).

15. **In regards to claim 15:** Bird discloses a breathing treatment apparatus as cited in paragraph 14. Additionally, Bird discloses that gas flow adjustment (Bird column 79, lines 47 to 50 and column 80, lines 7 to 9) to said apparatus is pre-set at factory (column 80, lines 34 to 40).

16. **In regards to claim 22:** Bird discloses a breathing treatment apparatus cited in paragraph 14. Additionally, Bird discloses that said patient interface circuit (figure 10) is, at least one of, connected to and incorporated with in a ventilator circuit (Bird, ABSTRACT).

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17. **In regards to claim 26:** Bird discloses a continuous high-frequency oscillation breathing treatment apparatus comprising a source of gas under pressure (Bird column 6, lines 1-3); a pre-set reduction regulator (Bird column 6, lines 46-48. Bird discloses a regulator set to reduce the pressure to approximately 50 psi, which is a pre-set value) for regulating the flow from gas source; means for interrupting continuous positive gas flow at a rate of least 1 hertz and at most 15 hertz (Bird column 9 line 60 to column 17 line 65. Bird is fully capable of meeting the claim limitations of at least 1 hertz and at most 15 hertz because of ability to adjust the frequency of oscillation; Bird column 34 lines 51-56), whereby the gas flow becomes pulsatile (Bird column 1 lines 26-29) with a substantially constant pressure amplitude ; a patient interface circuit that incorporates a fixed venturi tube (Bird column 7 lines 52-53) , encased in a shroud with at least one aperture of predetermined size (Bird column 29 lines 44-58), open to the ambient to allow to allow ingress and egress of flow, and an aerosol entrainment port (Bird column 30 lines 4-18) connectable to a nebulizer for entrainment of aerosol (Bird column 30 lines 29-61); said means for interrupting continuous gas flow in combination with said at least one aperture calibrated to allow exhalation and prevent stacking of successive volumes of gas in the airway of the patient (Bird column 29 line 62 to column 30 line 16).

18. **In regards to claim 33:** Bird discloses a breathing treatment apparatus cited in paragraph 17. Additionally, Bird discloses that said patient interface circuit (figure 10) is, at least one of, connected to and incorporated with in a ventilator circuit (Bird, ABSTRACT).

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19. **In regards to claim 37:** Bird discloses a continuous high-frequency oscillation breathing treatment apparatus comprising a source of gas under pressure (Bird column 6, lines 1-3); a reduction regulator (Bird column 6, lines 46-48) for regulating the flow from gas source; a patient interface circuit (974) that incorporates a means for interrupting positive gas flow at a rate of at least 1 hertz and at most 15 hertz (Bird column 9 line 60 to column 17 line 65. Bird is fully capable of meeting the claim limitations of at least 1 hertz and at most 15 hertz because of ability to adjust the frequency of oscillation; Bird column 34 lines 51-56), whereby the gas flow becomes pulsatile (Bird column 1 lines 26-29) with a substantially constant pressure amplitude, a fixed venturi tube (Bird column 7 lines 52-53), encased in a shroud with at least one aperture of predetermined size (Bird column 29 lines 44-58), open to the ambient to allow to allow ingress and egress of flow, and an aerosol entrainment port (Bird column 30 lines 4-18) connectable to a nebulizer for entrainment of aerosol (Bird column 30 lines 29-61); said means for interrupting continuous gas flow in combination with said at least one aperture calibrated to allow exhalation and prevent stacking of successive volumes of gas in the airway of the patient (Bird column 29 line 62 to column 30 line 16).

20. **In regards to claim 45:** Bird discloses a breathing treatment apparatus cited in paragraph 21. Additionally, Bird discloses that said patient interface circuit (figure 10) is, at least one of, connected to and incorporated with in a ventilator circuit (Bird, ABSTRACT).

Claim Rejections - 35 USC § 103

21. Claims 8, 10, 21, 23, 32, 34, 44, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird (USPN 4,592,349; 'Bird').

22. In regards to claim 8: Bird discloses a breathing treatment apparatus cited in paragraph 11. Additionally, Bird discloses a breathing apparatus wherein at least one aperture is designated as a primary for ingress of gas (864) and is connected to a specified gas source in order to control the content of the gas being entrained, and at least one aperture is designated as primary egress of gas (819) and is connected to a reservoir that collects the evacuated gas (It is well known in the art that evacuated gas can be collected in a reservoir and scavenged for harmful gasses.) and is open to the ambient.

23. In regards to claim 10: Bird discloses a breathing treatment apparatus cited in paragraph 11. Additionally, Bird discloses that said gas under pressure is supplied from compressor within the apparatus (Bird column 56, lines 56-61). Bird does not disclose expressly that said gas under pressure is supplied from an electric compressor within the apparatus.

24. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an electric compressor because Applicant has not disclosed that using an electric compressor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with either the claimed electric compressor or the compressor taught by Bird because both compressors perform the same

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function of pressurizing gas to be passed into the body. Therefore, it would have been an obvious matter of design choice to modify Bird to obtain the invention as specified in claim 10.

25. **In regards to claim 21:** Bird discloses a breathing treatment apparatus cited in paragraph 14. Additionally, Bird discloses a breathing apparatus wherein at least one aperture is designated as a primary for ingress of gas (864) and is connected to a specified gas source in order to control the content of the gas being entrained, and at least one aperture is designated as primary egress of gas (819) and is connected to a reservoir that collects the evacuated gas (It is well known in the art that evacuated gas can be collected in a reservoir and scavenged for harmful gasses.) and is open to the ambient.

26. **In regards to claim 23:** Bird discloses a breathing treatment apparatus cited in paragraph 14. Additionally, Bird discloses that said gas under pressure is supplied from compressor within the apparatus (Bird column 56, lines 56-61). Bird does not disclose expressly that said gas under pressure is supplied from an electric compressor within the apparatus.

27. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an electric compressor because Applicant has not disclosed that using an electric compressor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with either the claimed electric compressor or the compressor taught by Bird because both compressors perform the same

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function of pressurizing gas to be passed into the body. Therefore, it would have been an obvious matter of design choice to modify Bird to obtain the invention as specified in claim 23.

28. **In regards to claim 32:** Bird discloses a breathing treatment apparatus cited in paragraph 17. Additionally, Bird discloses a breathing apparatus wherein at least one aperture is designated as a primary for ingress of gas (864) and is connected to a specified gas source in order to control the content of the gas being entrained, and at least one aperture is designated as primary egress of gas (819) and is connected to a reservoir that collects the evacuated gas (It is well known in the art that evacuated gas can be collected in a reservoir and scavenged for harmful gasses.) and is open to the ambient.

29. **In regards to claim 34:** Bird discloses a breathing treatment apparatus cited in paragraph 17. Additionally, Bird discloses that said gas under pressure is supplied from compressor within the apparatus (Bird column 56, lines 56-61). Bird does not disclose expressly that said gas under pressure is supplied from an electric compressor within the apparatus.

30. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an electric compressor because Applicant has not disclosed that using an electric compressor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with either the claimed electric compressor or the compressor taught by Bird because both compressors perform the same

function of pressurizing gas to be passed into the body. Therefore, it would have been an obvious matter of design choice to modify Bird to obtain the invention as specified in claim 34.

31. **In regards to claim 44:** Bird discloses a breathing treatment apparatus cited in paragraph 21. Additionally, Bird discloses a breathing apparatus wherein at least one aperture is designated as a primary for ingress of gas (864) and is connected to a specified gas source in order to control the content of the gas being entrained, and at least one aperture is designated as primary egress of gas (819) and is connected to a reservoir that collects the evacuated gas (It is well known in the art that evacuated gas can be collected in a reservoir and scavenged for harmful gasses.) and is open to the ambient.

32. **In regards to claim 46:** Bird discloses a breathing treatment apparatus cited in paragraph 21. Additionally, Bird discloses that said gas under pressure is supplied from compressor within the apparatus (Bird column 56, lines 56-61). Bird does not disclose expressly that said gas under pressure is supplied from an electric compressor within the apparatus.

33. At the time the invention was made, it would have been an obvious matter of design choice to a person or ordinary skill in the art to use an electric compressor because Applicant has not disclosed that using an electric compressor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with either the claimed electric compressor or the compressor taught by Bird because both compressors perform the same

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function of pressurizing gas to be passed into the body. Therefore, it would have been an obvious matter of design choice to modify Bird to obtain the invention as specified in claim 46.

34. Claims 3, 4, 6, 16, 17, 19, 27, 28, 30, 39, 40, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird in view of Truitt et al. (USPN 6,581,596; "Truitt").

35. In regards to claim 3: Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention the ability to partially occlude at least one aperture in order to increase and decrease the ingress and egress of flow. Truitt teaches through the use of oscillatory occlusion of apertures, pressure can be altered creating pulsatile air conducive to clearing secretions from the patients airway (Truitt column 4 lines 14-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the aperture occluding device of Truitt in order to make the breathing apparatus more capable of clearing secretions from the airway of the patient.

36. In regards to claim 4: Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention a means to prevent inadvertent occlusion of said apertures. Truitt teaches that a casing (32) can be placed around the aperture in order to prevent the inadvertent occlusion of the aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the casing of Truitt in order to protect the aperture from inadvertently being occluded.

37. **In regards to claim 6:** Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention a means for tracking use of said apparatus, whereby patient compliance with breathing therapy can be ascertained. Truitt teaches that a timer that increments during use can be applied in order to monitor patient compliance and patient condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and timer of Truitt to monitor the progress and compliance of the patient using the device.

38. **In regards to claim 16:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention the ability to partially occlude at least one aperture in order to increase and decrease the ingress and egress of flow. Truitt teaches through the use of oscillatory occlusion of apertures, pressure can be altered creating pulsatile air conducive to clearing secretions from the patients airway (Truitt column 4 lines 14-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the aperture occluding device of Truitt in order to make the breathing apparatus more capable of clearing secretions from the airway of the patient.

39. **In regards to claim 17:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention a means to prevent inadvertent occlusion of said apertures. Truitt teaches that a casing (32) can be placed around the aperture in order to prevent the inadvertent occlusion of the aperture. It would have been obvious to one of ordinary skill in the art at the

time the invention was made to combine the breathing treatment apparatus of Bird and the casing of Truitt in order to protect the aperture from inadvertently being occluded.

40. **In regards to claim 19:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention a means for tracking use of said apparatus, whereby patient compliance with breathing therapy can be ascertained. Truitt teaches that a timer that increments during use can be applied in order to monitor patient compliance and patient condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and timer of Truitt to monitor the progress and compliance of the patient using the device.

41. **In regards to claim 27:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention the ability to partially occlude at least one aperture in order to increase and decrease the ingress and egress of flow. Truitt teaches through the use of oscillatory occlusion of apertures, pressure can be altered creating pulsatile air conducive to clearing secretions from the patients airway (Truitt column 4 lines 14-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the aperture occluding device of Truitt in order to make the breathing apparatus more capable of clearing secretions from the airway of the patient.

42. **In regards to claim 28:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention a means to prevent inadvertent occlusion of said apertures. Truitt

teaches that a casing (32) can be placed around the aperture in order to prevent the inadvertent occlusion of the aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the casing of Truitt in order to protect the aperture from inadvertently being occluded.

43. **In regards to claim 30:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention a means for tracking use of said apparatus, whereby patient compliance with breathing therapy can be ascertained. Truitt teaches that a timer that increments during use can be applied in order to monitor patient compliance and patient condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and timer of Truitt to monitor the progress and compliance of the patient using the device.

44. **In regards to claim 39:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention the ability to partially occlude at least one aperture in order to increase and decrease the ingress and egress of flow. Truitt teaches through the use of oscillatory occlusion of apertures, pressure can be altered creating pulsatile air conducive to clearing secretions from the patients airway (Truitt column 4 lines 14-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the aperture occluding device of Truitt in order to make the breathing apparatus more capable of clearing secretions from the airway of the patient.

45. **In regards to claim 40:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention a means to prevent inadvertent occlusion of said apertures. Truitt teaches that a casing (32) can be placed around the aperture in order to prevent the inadvertent occlusion of the aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the casing of Truitt in order to protect the aperture from inadvertently being occluded.

46. **In regards to claim 42:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention a means for tracking use of said apparatus, whereby patient compliance with breathing therapy can be ascertained. Truitt teaches that a timer that increments during use can be applied in order to monitor patient compliance and patient condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and timer of Truitt to monitor the progress and compliance of the patient using the device.

47. **Claims 7, 20, 32, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird in view of Riggs et al. (USPN 5,277,175 ; "Riggs").**

48. **In regards to claim 7:** Bird discloses a breathing treatment apparatus as cited in paragraph 11, but does not mention further including a medicament reservoir from which can be pumped medicament in to a nebulizer connected to patient interface circuit. Riggs teaches that a medicament stored in a large supply vessel (70) can be pumped from said large supply vessel by way of a pump (60) to a nebulizer vial (50) (Riggs column 8, lines 45-66). It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the nebulizer pumping system as described by Riggs for the purpose of have a breathing treatment apparatus that can run continuously without the need to stop for the reason of filling the nebulizer.

49. **In regards to claim 20:** Bird discloses a breathing treatment apparatus as cited in paragraph 14, but does not mention further including a medicament reservoir from which can be pumped medicament in to a nebulizer connected to patient interface circuit. Riggs teaches that a medicament stored in a large supply vessel (70) can be pumped from said large supply vessel by way of a pump (60) to a nebulizer vial (50) (Riggs column 8, lines 45-66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the nebulizer pumping system as described by Riggs for the purpose of have a breathing treatment apparatus that can run continuously without the need to stop for the reason of filling the nebulizer.

50. **In regards to claim 32:** Bird discloses a breathing treatment apparatus as cited in paragraph 17, but does not mention further including a medicament reservoir from which can be pumped medicament in to a nebulizer connected to patient interface circuit. Riggs teaches that a medicament stored in a large supply vessel (70) can be pumped from said large supply vessel by way of a pump (60) to a nebulizer vial (50) (Riggs column 8, lines 45-66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the nebulizer pumping system as described by Riggs

for the purpose of have a breathing treatment apparatus that can run continuously without the need to stop for the reason of filling the nebulizer.

51. **In regards to claim 43:** Bird discloses a breathing treatment apparatus as cited in paragraph 21, but does not mention further including a medicament reservoir from which can be pumped medicament in to a nebulizer connected to patient interface circuit. Riggs teaches that a medicament stored in a large supply vessel (70) can be pumped from said large supply vessel by way of a pump (60) to a nebulizer vial (50) (Riggs column 8, lines 45-66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the nebulizer pumping system as described by Riggs for the purpose of have a breathing treatment apparatus that can run continuously without the need to stop for the reason of filling the nebulizer.

52. **Claims 5, 18, 29, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird in view of McFarland, JR. (PGPub No. US2003/0121517 A1 ; “McFarland, JR.”).**

53. **In regards to claim 5:** Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention a timing device that can automatically turn off said apparatus at end of therapy session and trigger an alarm to notify patient that treatment session is over. McFarland JR. teaches that a patient programmable timer can be used to notify patient to the conclusion of their therapy session by means of a vibrating alarm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the timer/alarm of McFarland JR. to produce a breathing

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treatment apparatus that has an alarm that notifies the patient to the conclusion of their breathing therapy session.

54. **In regards to claim 18:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention a timing device that can automatically turn off said apparatus at end of therapy session and trigger an alarm to notify patient that treatment session is over. McFarland JR. teaches that a patient programmable timer can be used to notify patient to the conclusion of their therapy session by means of a vibrating alarm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the timer/alarm of McFarland JR. to produce a breathing treatment apparatus that has an alarm that notifies the patient to the conclusion of their breathing therapy session.

55. **In regards to claim 29:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention a timing device that can automatically turn off said apparatus at end of therapy session and trigger an alarm to notify patient that treatment session is over. McFarland JR. teaches that a patient programmable timer can be used to notify patient to the conclusion of their therapy session by means of a vibrating alarm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the timer/alarm of McFarland JR. to produce a breathing treatment apparatus that has an alarm that notifies the patient to the conclusion of their breathing therapy session.

56. **In regards to claim 41:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention a timing device that can automatically turn off said apparatus at end of therapy session and trigger an alarm to notify patient that treatment session is over. McFarland JR. teaches that a patient programmable timer can be used to notify patient to the conclusion of their therapy session by means of a vibrating alarm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the timer/alarm of McFarland JR. to produce a breathing treatment apparatus that has an alarm that notifies the patient to the conclusion of their breathing therapy session.

57. **Claims 11, 12, 24, 25, 35, 36, 47, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird in view of Smith et al. (PGPub No. US2005/0172954 A1 ; “Smith”).**

58. **In regards to claim 11:** Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention the apparatus wherein at least some of the components include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches that an aerosol generating apparatus can include an identification device for compatibility reasons (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the identification device of Smith to ensure the compatibility of the components of the apparatus.

59. **In regards to claim 12:** Bird discloses a breathing treatment apparatus cited in paragraph 11, but does not mention the apparatus wherein at least some of the components of the apparatus include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches RFID (radio frequency identifier) labels can be placed on the containers holding the medicament. Smith also teaches that said RFID labels are in communication with a controller via radio frequency (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the RFID labels of Smith so that the systems compatibility is not comprised with inappropriate medicines.

60. **In regards to claim 24:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention the apparatus wherein at least some of the components include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches that an aerosol generating apparatus can include an identification device for compatibility reasons (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the identification device of Smith to ensure the compatibility of the components of the apparatus.

61. **In regards to claim 25:** Bird discloses a breathing treatment apparatus cited in paragraph 14, but does not mention the apparatus wherein at least some of the components of the apparatus include an identification device to indicate their compatibility with other components of the

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apparatus. Smith teaches RFID (radio frequency identifier) labels can be placed on the containers holding the medicament. Smith also teaches that said RFID labels are in communication with a controller via radio frequency (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the RFID labels of Smith so that the systems compatibility is not comprised with inappropriate medicines.

62. **In regards to claim 35:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention the apparatus wherein at least some of the components include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches that an aerosol generating apparatus can include an identification device for compatibility reasons (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the identification device of Smith to ensure the compatibility of the components of the apparatus.

63. **In regards to claim 36:** Bird discloses a breathing treatment apparatus cited in paragraph 17, but does not mention the apparatus wherein at least some of the components of the apparatus include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches RFID (radio frequency identifier) labels can be placed on the containers holding the medicament. Smith also teaches that said RFID labels are in communication with a controller via radio frequency (Smith paragraph 51 and paragraph 66). It

would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the RFID labels of Smith so that the systems compatibility is not comprised with inappropriate medicines.

64. **In regards to claim 47:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention the apparatus wherein at least some of the components include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches that an aerosol generating apparatus can include an identification device for compatibility reasons (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the identification device of Smith to ensure the compatibility of the components of the apparatus.

65. **In regards to claim 48:** Bird discloses a breathing treatment apparatus cited in paragraph 21, but does not mention the apparatus wherein at least some of the components of the apparatus include an identification device to indicate their compatibility with other components of the apparatus. Smith teaches RFID (radio frequency identifier) labels can be placed on the containers holding the medicament. Smith also teaches that said RFID labels are in communication with a controller via radio frequency (Smith paragraph 51 and paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the breathing treatment apparatus of Bird and the RFID labels of Smith so that the systems compatibility is not comprised with inappropriate medicines.

Claim Rejections - 35 USC § 112

66. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

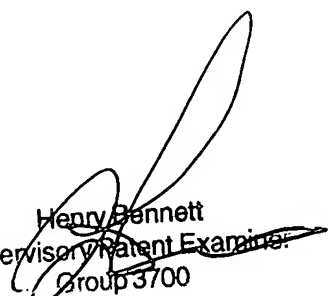
67. **Claims 2, 38 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the metes and bounds of the claim.** The phrase “the optimal settings” does not disclose any boundaries to which the device will be configured. The specification does not cite any reference to “the optimal settings”, thus no boundaries can be inferred to from the specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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